

REMARKS:

1. In general:

Applicants note that the May 5 Office Action has withdrawn certain rejections made in a previous Office Action mailed by the PTO on November 25, 2003. These include rejections made under 35 U.S.C. §§ 102 and 103.

2. Claim rejections under 35 U.S.C. § 112 ¶ 1:

The May 5 Office Action states that the amended claims stand rejected under 35 U.S.C. § 112 ¶1. According to the May 5 Office Action: "The claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. (May 5 Office Action at 2.) Applicant respectfully traverses this rejection.

First, Applicants note the Office Action mailed August 26, 2003 and Applicants' response and amendment to the August 26 Office action filed November 25, 2003. The August 26 Office Action states: "Claims 20-28 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an agent for treating psoriasis and contact dermatitis utilizing a KPV composition, does not reasonably provide enablement for an agent which prevents psoriasis and contact dermatitis." (Paper 19 at 4.) Applicants traversed the rejection and do not agree with the August 26 Office Action that claims 20-28 are not enabled. In an effort to further the application towards issuance, Applicants canceled claims 20-28 and amended claims 1-2 and 7-8

to "treatment of psoriatic disorders and contact dermatitis" which, according to the August 26 Office Action, were adequately enabled.

Second, the May 5 Office Action states that the claimed invention requires undue experimentation as: "However, there is no indication that the combination of the two compounds into one formulation would adequately control inflammation and microbial loads." (May 5 Office Action at 4.) Respectfully, Applicants do not agree. However, to further the favorable prosecution of this application, Applicants will avoid here highly technical arguments relating to the mechanism of action of the claimed invention, (which is adequately disclosed in the instant specification (hereon, "Specification") at pages 9-12), and point out, simply, the claims as amended are directed to psoriasis and contact dermatitis, two ailments that do not relate to a "microbial load."

Third, the May 5 Office Action further addresses "the state of the art and the predictability or lack thereof in the art." (Office Action at 4). The Specification describes psoriasis as: "The pathophysiology of the syndromes includes a marked decrease in epidermal turnover time resulting in a markedly increased number of mitotic cells in the dividing pool." (Specification at 2.) The description of the pathogenesis of psoriasis goes into more detail in pages 2-3 of the Specification, citing as authority Fitzpatrick, et al., Color Atlas and Synopsis of Clinical Dermatology, McGraw Hill Book Co. (1983); and Barker Burton and Zieve, Principles in Ambulatory Medicine, Williams and Wilkins (1982). A brief review of these areas of the Specification will confirm that psoriasis is not an infective process subject to a microbial load.

The same is true with contact dermatitis. Example III demonstrates the use of one aspect of the claimed invention on contact dermatitis. (Specification at 20-21). Specifically, the Example states: "There was no evidence of secondary infection or open wounds or cellulitis." (Specification at 20.) Incidentally, Example III discloses the fact that contact dermatitis *can* lead to secondary infection. In the example at hand, no infection developed.

Fourth, the May 5 Office Action further addresses "the amount of direction or guidance present and the presence of working examples." The May 5 Office Action focuses on a lack of direction with regard to KPV as an anti-microbial and anti-inflammatory. Respectfully, Applicants disagree. Nevertheless, the amended claims are directed to psoriasis and contact dermatitis which are not microbial processes. In this respect, the Specification contains examples directed to both psoriasis and contact dermatitis. (Specification at Examples II and III, pages 18-21.) The Examples provide treatment modalities of the claimed afflictions. The Specification at pages 10 through 16 discloses numerous embodiments of making and using the invention.

Finally, with respect to § 112 ¶ 1, the May 5 Office Action further addresses "the breadth of the claims and the quantity of experimentation needed." (May 5 Office Action at 4.) The May 5 Office Action again places emphasis on the area of "situations where anti-inflammatories are required in conjunction with anti-microbials like the claimed KPV compounds...." (The May 5 Office Action at 4.) Applicants note that contact dermatitis and psoriasis are not "situations where anti-inflammatories are required in conjunction with anti-microbials. They are not infective "situations." It is well

established in the art that one of the first line treatments for inflammatory pathology are glucocorticoids. The application teaches the advantages of controlling the inflammatory process with KPV and glucocorticoids.

3. The May 5 Office Action withdraws the rejection of claims 1-20 under 35 U.S.C. § 112 ¶ 1.

Acknowledged.

4. The May 5 Office Action withdraws rejections of claims 1-4, 7-9, 20-23.

Acknowledged.

5. Claim rejections under 35 U.S.C. § 102(b) are withdrawn for claims 1-2.

Acknowledged.

6. Claim rejections under 35 U.S.C. § 103 are withdrawn for claims 1-4 and 7-9.

Acknowledged.

In view of the foregoing, it is submitted that the claims are in condition for allowance, and a Notice of Allowance is requested.

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Respectfully submitted,

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